UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,700	12/06/2005	Hajime Nakazawa	P1446US	2871

1218 7590 10/30/2008

CASELLA & HESPOS
274 MADISON AVENUE
NEW YORK, NY 10016

EXAMINER	
MARCETICH, ADAM M	
ART UNIT	**PAPER NUMBER**
3761	

MAIL DATE	DELIVERY MODE
10/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,700	NAKAZAWA ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06 December 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Claims 14-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 August 2008. Claims 1-13 are evaluated on the merits.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Japan 2003-165277, filed on 10 June 2003 has been received.

Specification

3. The abstract of the disclosure is objected to because references to drawing features should be placed within parenthesis for clarity. Correction is required. See MPEP § 608.01(b). Also see PCT Rule 8, The Abstract, available in MPEP 1826.

4. 8.1(d) Each main technical feature mentioned in the abstract and illustrated by a drawing in the international application shall be followed by a reference sign, placed between parentheses.

35 USC § 112, 6th Paragraph

5. With regard to Applicant's "means for pressure reduction means for reducing a residual pressure" of claims 6 and 7, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:

(A) The claim limitations must use the phrase "means for" or "step for;"

(B) the "means for" or "step for" must be modified by functional language; and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

In the instant case, Examiner considers the button 88 and strap 90 of Rygiel (US Patent 4,397,643) to be an equivalent to the "pressure reduction means for reducing a residual pressure" disclosed by applicant, since it performs the same function (opening

a receptacle) in the same way (increasing a volume of the interior space of said receptacle), with the same result (reducing a residual pressure) as the device disclosed by Applicant. For example, the immediate specification discloses opening cover body 15, which increases an interior volume of receptacle 600 and reduces residual pressure (p. 25, ¶ 5). Additionally, the button 88 and strap 90 of Rygiel is the structural equivalent of the tongue portion 15e and engagement pawl 23 as depicted on Fig. 1 of the drawing sheets. See MPEP 2183.

6. Regarding claims 6 and 7, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification. Examiner finds support in the immediate specification on: p. 5, ¶ 6; p.25, ¶ 5; and p.26, ¶ 4.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Olson (US Patent 5,275,585).

9. Regarding claim 1, Olson discloses a receptacle for use with a medical suction device (col. 2, lines 47-52, Fig. 1, autotransfusion system 10);

which is equipped with a rigid case for detachably holding and air-tightly surrounding at least a portion of said receptacle (col. 3, lines 15-26, Figs. 4-7, rigid receptacle 16); and

a patient-side tube for introducing waste liquid into said receptacle (col. 3, lines 15-26, Figs. 4-7, blood inlet tube 20);

designed to create a negative pressure in both an interior space of said rigid case and an interior space of said receptacle so as to allow waste liquid to be sucked into said receptacle through said patient-side tube (col. 3, lines 15-26, Figs. 4-7, MOPVS 14 for creating negative pressure);

said receptacle comprising:

an air-pervious/liquid-impervious element having air perviousness and liquid imperviousness (col. 3, lines 37-42, Fig. 6, hydrophobic vent 32); and,

said air-pervious/liquid-impervious element at least partly constituting at least the portion of said receptacle to be surrounded by said rigid case (Fig. 6, hydrophobic vent 32 surrounded by rigid receptacle 16);

said air-pervious/ liquid-impervious element being adapted to discharge an air in the interior space of said receptacle to the interior space of said rigid case in response to the negative pressure created in the interior space of said rigid case (col. 3, lines 37-42, Fig. 6, hydrophobic vent 32 allowing air to pass through while blocking liquid).

10. Regarding claim 2, Olson discloses a receptacle which further includes a check valve adapted to allow waste liquid sucked from said patient-side tube to flow into the

interior space thereof (col. 3, lines 51-64, especially lines 57-59, Figs. 4-5, suction port 46 and exhaust port 48 both comprising one-way valves not depicted), and

prevent said sucked waste liquid from flowing out to said patient-side tube (it is the Examiner's position that check valves limit backwards flow from collection bag 26 within rigid receptacle 16 as depicted).

11. Regarding claim 3, Olson discloses a receptacle wherein said air-pervious/liquid-impervious element is located below a connection position with said patient-side tube in the state after being held by said rigid case (Fig. 6, hydrophobic vent 32 located below connection with blood inlet tube 20).

12. Regarding claim 4, Olson discloses a receptacle wherein said air-pervious/liquid-impervious element is located at a position corresponding to a liquid level for a target suction volume of waste liquid, in the state after being held by said rigid case (Fig. 6, blood collection bag 26 capable of filling with blood up to level of hydrophobic vent 32).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,275,585) in view of Rygiel (US Patent 4,397,643).

16. Regarding claims 6 and 7, Olson discloses the invention as substantially claimed, see above. However, Olson lacks pressure reduction means for reducing a residual pressure as claimed [claims 6 and 7]. Rygiel discloses a drainage collection device comprising a rigid case and flexible bag (cols. 1-2, lines 55-2, 27-49, especially lines 32-37, Fig. 1, container 16 and liner 14), further comprising:

[6] pressure reduction means for reducing a residual pressure in the interior space thereof after completion of the waste-liquid collecting operation (col. 4, lines 51-58, 4, embodiment of canister 60 having button 88 and strap 90); and

[7] wherein said pressure reduction means is adapted to increase a volume of the interior space of said receptacle so as to reduce said residual pressure (it is the Examiner's position that opening button 88 and strap 90 increases the volume of canister 60, therefore reducing residual pressure). Rygiel provides the advantage of quickly securing or opening a container. To clarify, a clasp or button-type latch is faster to manipulate than a threaded opening as disclosed by Olson. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson as discussed with the pressure reduction means as taught by Rygiel in order to quickly secure or open a container.

17. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,275,585) in view of Manica et al. (US Patent Application Publication No. 2002/0138066), further in view of Blake (US Patent 6,077,233).

18. Regarding claims 12 and 13, Olson discloses the invention as substantially claimed, see above. However, Olson lacks a coagulating agent and partition portion as claimed [claims 12 and 13]. Manica discloses a system for decontaminating blood or blood components with a pathogen inactivation agent (¶ [0003], [0004], [0013]), further comprising:

[13] a partition portion for partitioning the interior space of said receptacle into a waste-liquid receiving chamber for collecting waste liquid therein (¶ [0056], Fig. 3, removable seal assembly 35); and

[13] an agent storage chamber for storing said agent (¶ [0056], [0058], Fig. 3, sub-compartment 14 for storing solution A);

[13] said partition portion being adapted to provide fluid communication between said waste-liquid receiving chamber and said coagulating- agent storage chamber according to a given operation of a user (¶ [0058], Fig. 3, providing fluid communication between sub-compartments 12 and 14 through removing removable seal assembly 35). Manica provides the advantage of quickly combining blood with an active agent. Additionally, Manica provides the advantage of separating a caregiver from blood-borne pathogens since the mixing step does not involve opening a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

made to modify the invention of Olson as discussed with the partition portion as taught by Manica in order to quickly add an active agent while protecting a caregiver.

Manica solves the problem of storing blood and inactivating pathogens. While Manica discloses anticoagulant solution stored within a chamber instead of the claimed coagulant, this provides the same advantage of treating blood during collection. Examiner notes that the claims are drawn to a receptacle, not the specific contents of a receptacle.

Olson in view of Manica discloses the invention substantially as claimed, see above. However, Olson in view of Manica lacks a coagulant as claimed [claim 12]. Blake discloses a blood coagulation test kit (col. 1, lines 5-22) further comprising [12] coagulating agent adapted to coagulate collected waste liquid (col. 4, lines 58-62, thrombogenic material such as collagen).

Blake solves the problem of coagulating blood within a chamber, especially a chamber that originally has coagulant disposed within it. Although Blake performs diagnostic testing on blood while the present invention coagulates blood for the purpose of sequestering or storing waste liquid, one would look to the teaching of Blake for an example of predisposed or prepackaged coagulant. the test unit 14 of Blake performs the same function of coagulating blood when it is introduced into a chamber. By providing a coagulant disposed within a container, Blake provides the advantage of rapidly reacting blood and avoiding the step of adding additional reactants, agents or materials to a chamber. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson in view of

Manica as discussed with the coagulant as taught by Blake in order to obviate or avoid an additional step of adding coagulant.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,275,585) in view of Bormann et al. (US Patent Application Publication No. 2002/0029021).

20. Regarding claim 10, Olson discloses the invention as substantially claimed, including:

a bag-shaped sheet having air-imperviousness and liquid-imperviousness (col. 1, lines 29-31; col. 2, lines 47-52; col. 3, lines 37-42; Figs. 1, 6; collection bag 26 requiring vents to pass air, and therefore being substantially air-impervious); and

said sheet being adapted to collect waste liquid in an interior space thereof (Figs. 1, 6; collection bag 26 adapted to collect liquid). However, Olson lacks a communication member as claimed [claim 10]. Bormann discloses a device for transferring fluid (¶ [0021], [0022], [0033], Fig. 4, device 100), further comprising a communication member for forming a passage (¶ [0033], Fig. 4, housing 14 comprising porous medium 10);

which provides fluid communication between the interior and exterior spaces of a chamber (Fig. 4, porous medium 10 dividing interior and exterior portions of housing 14 as depicted);

wherein an air- pervious/liquid- impervious element is incorporated in said communication member in such a manner as to close said passage (¶ [0046]-[0048], porous medium 10 preventing overfilling when wetted by rising liquid level).

Bormann provides the advantage of closing a collection system based on a rising fluid level, which prevents overfilling (¶ [0046]-[0048], porous medium 10 preventing overfilling when wetted by rising liquid level). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson as discussed with the communication member as taught by Bormann in order to prevent overfilling.

Regarding the limitation of bag-shaped sheet as claimed [claim 10], Examiner notes that no additional structure is being claimed. To clarify, collection bag 26 of Olson is interpreted as the bag-shaped sheet of claim 10, and porous medium 10 of Bormann is interpreted as the communication member of claim 1.

21. Claims 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,275,585) in view of Verkaart (US Patent 4,466,888).

22. Regarding claim 5, Olson discloses the invention as substantially claimed, see above. However, Olson lacks an air- pervious/liquid-impervious element located as claimed [claim 5]. Verkaart discloses a blood collection assembly having a rigid outer case and inner flexible bag (col. 3, lines 48-52, 59-65; Figs. 1-3, shells 20 and 22 and collection bag 30) further comprising:

an air- pervious/liquid-impervious element located over a given range below said liquid level for the target suction volume of waste liquid, in the state after being held by said rigid case (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 located over range extending below a liquid level for the target suction volume of liquid when held within shells 20 and 22). Verkaart provides the advantage of removing foam from collected blood (col. 5, lines 19-28). This is relevant to the problem of collecting and disposing of blood, since foamed blood may harbor pathogens that will pass into a suction pump or vacuum line. In other words, the air- pervious/liquid-impervious element of Verkaart prevents pathogens from exiting a collection bag as foam.

23. Regarding claim 8, Olson discloses the invention as substantially claimed, see above. However, Olson lacks a second sheet and rigid port portion as claimed [claim 8]. Verkaart discloses:

[8, 9] a first sheet having air-imperviousness and liquid-imperviousness (cols. 4-5; Fig. 4, bag membrane having plastic faces);

[8] a second sheet including an air-pervious/liquid-impervious element and having a peripheral edge joined to a peripheral edge of said first sheet (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 sealed to peripheral edges of plastic bag faces);

[9] a second sheet having air-perviousness and liquid-imperviousness to serve as said air-pervious/liquid-impervious element,

[9] said second sheet having a peripheral edge joined to a peripheral edge of said first sheet (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 sealed to peripheral edges of plastic bag faces);

[8, 9] a rigid port portion joined between said first and second sheets and adapted to form a part of a passage for introducing waste liquid between said first and second sheets (col. 6, lines 51-64; Fig. 8, inlet fitting 110 and filter screen 100 heat sealed between front and rear bag faces as depicted);

[8, 9] wherein said receptacle is designed to allow said first and second sheets to be entirely surrounded by said rigid case (cols. 3-4, lines 67-9; Figs. 1-3, bag 30 placed within front and rear shells 20 and 22);

[8, 9] while air-tightly attaching an outer peripheral surface of said port portion to said rigid case (col. 4, lines 10-21, connecting fluid inlet fitting 40 and fitting 50). Verkaart provides the advantage of removing foam from collected blood. Regarding rationale and motivation, see discussion of claim 5 above.

Regarding the limitation of a second sheet including an air-pervious/liquid-impervious element, Examiner interprets the blockage of foamed liquid as being substantially liquid-impervious.

Filter 70 of Verkaart is interpreted as the second sheet of both claims 8 and 9, since no additional structure is claimed. To clarify, filter 70 of Verkaart is interpreted as a second sheet for both claims 8 and 9, since the claims do not depend on each other.

24. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olson (US Patent 5,275,585) in view of Verkaart (US Patent 4,466,888), further in view of Manica et al. (US Patent Application Publication No. 2002/0138066).

25. Regarding claim 11, Olson in view of Verkaart discloses the invention as substantially claimed, see above. However, Olson in view of Verkaart lacks a fastening element as claimed [claim 11]. Manica discloses a receptacle which further includes:

a fastening element for fastening a folded portion of said sheet to prevent said folded portion from being unfolded (¶ [0066], [0067], Figs. 15, 16, removable clamp 710);

said fastening element being designed to release the fastened state of said folded portion in response to expansion of said receptacle which is caused by a difference between a pressure in a space located inside said rigid case and outside said receptacle and a pressure in the interior space of said receptacle (¶ [0069], Figs. 15, 16, removable clamp 710 removed to combine fluids within separate chambers of container 700);

occurring in an initial stage of the creation of a negative pressure in the interior space of said rigid case (Examiner notes that clamp 710 may be removed at an initial stage).

Manica provides the advantage of storing active agents separately during storage (end of ¶ [0068], compartments aiding in oxidation reactions after removal of clamp 710). In other words, storing agents separately allows a longer storage life, since the reactants are held in an unmixed, unreacted state. Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Olson in view of Verkaart as discussed with the fastening element as taught by Manica in order to store active agents separately, and prolong their shelf life.

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Doherty; George O. US 3648698
- Berman; Richard M. et al. US 3946739
- May; Edwin A. US 4058123
- Mohiuddin; Mahmood et al. US 6364864
- Gollier, Paul-Andre et al. US 20040078023

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

//Leslie R. Deak//
Primary Examiner, Art Unit 3761
10 October 2008